FILED

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

2008 FEB -5 P 4: 37

TRIANTAFYLLOS TAFAS, Plaintiff, **v.** **JON. W. DUDAS, *et al.*,** Defendants.	**1:07cv846 (JCC/TRJ)**

CONSOLIDATED WITH

SMITHKLINE BEECHAM CORPORATION, *et al.*, Plaintiff, **v.** **JON. W. DUDAS, *et al.*,** Defendants.	**1:07cv1008 (JCC/TRJ)**

MEMORANDUM OF *AMICUS CURIAE* DR. RON D. KATZNELSON IN OPPOSITION TO DEFENDANT'S MOTION TO STRIKE EXHIBITS

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1 INTRODUCTION

I, Ron D. Katznelson of Encinitas, California, *pro se*, submits this opposition brief ("Opposition") as *amicus curiae* in opposition to the January 22, 2008 Defendants' Motion to Strike Exhibit 1 and Appendices A – E (my "Exhibits") of my brief in support of the Tafas and GSK plaintiffs' motions for summary judgment (my "Brief"). As further explained herein and contrary to Defendants ("USPTO") assertions, my Exhibits are properly before the Court in order to assist and facilitate its judicial review.

2 STANDARD OF REVIEW

Among other statutes, an agency informal rulemaking actions are reviewed under the Administrative Procedure Act's ("APA") 'arbitrary and capricious' standard, 5 U.S.C. §706(2)(A). In its opinion in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420, (1971) ("*Overton Park*"), the U.S. Supreme Court stated that APA judicial "review is to be based on the full administrative record that was before the [agency] at the time [it] made [its] decision. But since the bare record may not disclose the factors that were considered or the [agency's] construction of the evidence it may be necessary for the District Court to require some explanation in order to determine if the [agency] acted within the scope of [its] authority and if the [agency's] action was justifiable under the applicable standard".[1]

In its Motion to Strike my Exhibits, the USPTO relies on the opinion in *Camp v. Pitts*, 411 U.S. 138, 142 (1973), ("*Camp*"), as support for its assertion that my Exhibits are not properly before the Court and that judicial review should be limited only to the record that the USPTO deemed appropriate to present to the Court.[2] However, the opinion in *Camp* was directed narrowly to proscribing a full *de-novo* judicial proceeding, but not to limit less intrusive measures for augmenting the record. *Camp* not only acknowledges that it does not foreclose on supplementation of the record furnished by an agency, but it makes clear that what is placed before a court by an agency is not necessarily the administrative record "in existence" for review in *Overton Park* sense: "If, as the Court of Appeals held and as the Comptroller does not now contest, there was such failure to explain administrative action as to frustrate effective judicial review, the remedy was ..., as contemplated by Overton Park, to obtain from the agency, either through ***affidavits*** or ***testimony***, such ***additional*** explanation of the reasons for the agency decision as ***may prove necessary***") (*Camp*, 411 U.S. 142-143, emphasis added). Thus, the quote from *Camp* cited by the USPTO should also be appropriately read as stating that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially [by the agency] in the reviewing court".

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[1] The Court never specifically defines the term "record" except to identify it with the ***full*** information before the agency at the time it made its decision. Contrast this non-specific account with the notion of 'record' in formal proceedings described in 5 U.S.C. §§556-57.

[2] Defendants' Motion to Strike, Dkt. No. 250, at 5, (January 22, 2008). (hereinafter "Defn. Mot.")

In its Motion, the USPTO also cites *Florida Power & Light Co. v. Lorian*, 470 U.S. 729, 744 (1985), in which the Court casually refers to the record for review as " the record the agency presents to the reviewing court." In that case, however, there is no indication that the Court had in mind a situation in which such a record did not reflect the full record. This is evident from the same page of its opinion in which the *Lorian* Court calls for remand to the agency for additional investigation or explanation "If the ***record before the agency*** does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of ***the record before it***".[3] (Emphasis added). This clearly is the *Overton Park* view, prescribing circumstances under which augmentation of the agency record must be ordered. It is not in keeping with *Overton Park* or with subsequent Supreme Court and lower court opinions to believe that by, unilateral action, an agency can define the boundaries of the record for judicial review or withhold from a reviewing court information that it considered but which undercuts its decision.[4]

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[3] *Lorian*, 470 U.S. at 744.

[4] *Bar MK Ranches v Yeutter*, 994 F.2d 735, 739 (10th Cir. 1993) ("An agency may not unilaterally

While *Overton Park* commands judicial scrutiny confined to the full record, it makes clear in the same passage that it also requires "a thorough, probing, in-depth review."[5] Thus, not only must a reviewing court understand the material it analyzes in the record, but according to the Court in *Overton Park*, a reviewing court must assure itself that the agency has given adequate consideration to the "relevant factors".[6] In so doing, the Supreme Court in *State Farm* commanded reviewing courts to ascertain that the agency had not "***entirely*** failed to consider an important aspect of the problem".[7] But aspects of the problem that the agency ***entirely*** failed to consider are unlikely to be found in the record assembled by the agency. The seeming epistemological contradiction with strict "On the Record Rule" is that, by definition, a record cannot establish its own completeness. Based on a plausible definition of "relevant factors" and those entirely not considered by an agency, a court cannot determine what was not considered by an agency solely by examining a record of what was. If it cannot do so, how can a court both engage in relevant factors analysis and follow the strict On the Record Rule? It cannot, and therefore the law fashioned by the Supreme Court in *Overton Park* and in *State Farm*, heralded jurisprudence under which exceptions were established in the law for augmenting the record beyond that provided by the agency.

In *Esch v. Yeutter*, 876 F.2d 976, 991 (D.C. Cir. 1989), the Court identified eight circumstances of exceptions countenancing use of extra-record evidence: "(1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; (3) when an agency considered evidence which it

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determine what constitutes the Administrative Record"); *Exxon Corp. v. Department of Energy*, 91 F.R.D. 26, 32 (N.D.Tex.1981) (The whole administrative record "is not necessarily those documents that the agency has compiled and submitted as 'the' administrative record." .... "The 'whole' administrative record, therefore, consists of all documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Id.* at 33); *National Wildlife Federation v. Burford*, 677 F.Supp. 1445, 1457 (D.Mont. 1985) ("An agency may not submit an administrative record to the court which contains only documents favoring the agency's decision and omits documents present in the agency's file which bear upon matters before the court").

[5] *Overton Park*, 401 U.S. at 415.

[6] *Id.* at 416.

[7] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("*State Farm*").

failed to include in the record; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly; (5) in cases where evidence arising after the agency action shows whether the decision was correct or not; (6) in cases where agencies are sued for a failure to take action; (7) in cases arising under the National Environmental Policy Act; and (8) in cases where relief is at issue, especially at the preliminary injunction stage." Not all these enumerated exceptions are relevant in this action. Moreover, courts have developed other closely related exceptions, as described below. Exceptions most relevant to this case are discussed below.

2.1 When agency action is not adequately explained

If an agency fails to explain its decision adequately, a reviewing court can require testimony of administrative officials as to the reasons for reaching the decision. See *Overton Park* (401 U.S. at 420). When there is "such a failure [by the agency] to explain administrative action [so] as to frustrate effective judicial review".[8] Lower courts have thus invoked this exception as well.[9]

2.2 When the agency failed to consider relevant factors

On occasion, courts find it necessary to go beyond the On-the-Record Rule in order to perform "relevant factor analysis". There are cases in which the court's opinion leaves reason to believe that evidence was admitted under a relevant factors exception to *Overton Park's* On the Record Rule,[10] and still other cases, which may endorse such an exception in dicta.[11] One clear example of a case recognizing a "relevant factors" exception is *Conservation Law Foundation of New England. v. Clark.*[12] In that case, the court allowed production of affidavits of experts and other material not before the agency at the time of its decision, so that it could determine whether the agency had performed an adequate analysis of relevant factors. In *Asarco, Inc. v. U.S. Environmental Protection Agency*, 616 F.2d 1153, 1160 (9th Cir. 1980), the court stated:

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[8] *Camp*, 411 U.S. at 142-143.

[9] This exception is also articulated in *Esch* (876 F.2d at 991) as element (a) cited above. *See also Madison County Bldg. & Loan Ass'n v. Federal Home Loan Bank Bd.*, 622 F.2d 393 (8th Cir. 1980) (recognizing *Overton Park's* requirement for adequate agency explanation of its action but finding that no hearing of extra record evidence was required in the case); *Niam v. Ashcroft*, 354 F.3d 652, 660 (7th Cir. 2004) (Posner, J.) (If a document tends to show that the agency's "administrative record" is unexplained or unsupported "junk science," extra-record evidence may be considered.)

[10] *See Love v. Thomas*, 838 F.2d 1059 (9th Cir. 1988) (specifically approving augmentation under relevant factor exception), aff'g in part and rev'g in part on other grounds, 668 F. Supp. 1443, 1448-51 (D. Or. 1987) (allowing augmentation of record to evaluate whether agency took into account all relevant factors, looked at data readily available to, but not considered by agency, and described what agency would have found if agency had conducted a minimal investigation); *Arkla Exploration Co. v. Texas Oil & Gas Corp.*, 734 F.2d 347, 357 (8th Cir. 1984) (upholding district court's supplementation of record, among other reasons, to determine whether all relevant factors were considered), cert. denied, 469 U.S. 1158 (1985); *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160-62 (9th Cir. 1980) (asserting that district court

> "It will often be impossible, especially when highly technical matters are involved, for the court to determine whether the agency took into consideration all relevant factors unless it looks outside the record to determine what matters the agency should have considered but did not. The court cannot adequately discharge its duty to engage in a "substantial inquiry" if it is required to take the agency's word that it considered all relevant matters."

Extra-Record supplementation is not intended to correct or replace the factors considered by the agency but rather to provide background or explanatory information identifying relevant factors

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"went too far in consideration of evidence outside the administrative record," but finding extra record material admissible); *Hough v. Marsh*, 557 F. Supp. 74, 84 n.12, 86 n.17 (D. Mass. 1982) (finding it necessary to go beyond record to consider material bearing on whether agency sufficiently considered all relevant factors); *Hiatt Grain & Feed, Inc. v. Bergland*, 446 F. Supp. 457, 467 (D. Kan. 1978), aff'd, 602 F.2d 929 (10th Cir. 1979), cert. denied, 444 U.S. 1073 (1980).

[11] *Sierra Club v. United States Dep't of Transp.*, 695 F. Supp. 460, 463-64 (N.D. Cal. 1988) (recognizing relevant factor exception while using background information exception), rev'd on other grounds, 948 F.2d 568 (9th Cir. 1991); *AT&T Information Systems v. GSA*, 810 F.2d 1233, 1235-36 (D.C. Cir. 1981) (recognizing exception to enable court to determine whether agency considered all relevant factors--but not using such exception); *Environmental Defense Fund v. Costle*, 657 F.2d 275, 285-86 (D.C. Cir. 1981) (recognizing exception to exclusivity of administrative record where necessary to determine if agency considered relevant factors); *American Legion v. Derwinski*, 827 F. Supp. 805, 811-12 (D.D.C. 1993) (recognizing relevant factor exception, admitting extra-record material as explanation of decision), aff'd, 54 F.3d 789, 811 (D.C. Cir. 1995), petition for cert. filed, (Aug. 11, 1995); *Southern Utah Wilderness Alliance v. Thompson*, 811 F. Supp. 635, 642 n.4 (D. Utah 1993) (reviewing exceptions to On the Record Rule, including information relevant to whether agency failed to consider "relevant evidence," but not allowing supplementation); *Saint James Hosp. v. Heckler*, 579 F. Supp. 757, 762 (N.D. Ill. 1984) (discussing plaintiff's arguments and applicable law which argues for admission of litigation affidavits based inter alia on need to determine consideration of relevant factors, but refusing to admit them because record was sufficient to decide case), aff'd, 760 F.2d 1460 (7th Cir.), cert. denied, 474 U.S. 902 (1985); *Abington Memorial Hosp. v. Heckler*, 576 F. Supp. 1081, 1087 n.3 (E.D. Pa. 1983), aff'd, 750 F.2d 242 (3d Cir. 1984), cert. denied, 474 U.S. 863 (1985) (acknowledging *Asarco* exceptions for background information or information bearing on consideration of relevant factors, but refusing to consider plaintiff's affidavit which went to merits of agency's decision); *No Oilport! v. Carter*, 520 F. Supp. 334, 345-37 (W.D. Wash. 1981) (recognizing relevant factors exception but actually justifying admission based on special nature of NEPA and on need for agency to explain its decision as in *Overton Park*; allowing affidavits to establish adequacy of Environmental Impact Statement and to assist in explication of agency's decision in NEPA case).

[12] *Conservation Law Found. v. Clark*, 590 F. Supp. 1467, 1474-75 & n.5 (D. Mass. 1984), aff'd sub nom., *Conservation Law Found. v. Secretary of Interior*, 864 F.2d 954 (1st Cir. 1989).

that the agency should have considered:

> "Although the record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency... we have made clear that the new material should be merely explanatory of the original record." What does "explanatory of the original record" mean?: (1) explanatory of its true contents, or (2) explanatory of how the agency rationalized its decision based on the record. Neither such explanation would be a true exception, inconsistent with Overton Park's On the Record Rule."[13]

2.3 When an agency considered evidence which it failed to include in the record

Because the agency's decision must be evaluated based on the "whole record," 5 U.S.C. §706, where the record presented to a court does not reflect the actual record considered by the agency, the Court cannot decide whether the agency's decision was arbitrary or capricious.[14] Additionally, an incomplete record prevents judicial review of whether the agency followed appropriate procedural requirements. *Higgins v. Kelley*, 574 F.2d 789, 793 (3d Cir.1978).

Therefore, supplementation is proper when an agency considered evidence which it failed to include in the record. *Esch*, 876 F.2d at 991. When the agency may have deliberately or negligently omitted documents that may have been adverse to its decision, those documents must be considered. *Kent County v. U.S. Environmental Protection Agency*, 963 F.2d 391, 395-96 (D.C.Cir.1992); *Amfac Resorts LLC v. Dep't of Interior*, 143 F.Supp.2d 7, 11-12 (D.D.C. 2001). In *Exxon Corp. v. Department of Energy*, 91 F.R.D. 26, 34 (N.D.Tex.1981), the court concluded that discovery was available because "Exxon [had] made a strong showing that the Administrative Record certified to this Court is incomplete. Incompleteness is evident from the record's face."[15]

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[13] *AT&T Information Systems, Inc. v. General Services Admin.*, 810 F.2d 1233, 1236 (D.C. Cir. 1987).

[14] *Overton Park*, 401 U.S. at 419-20; *See also id.* at 423 ("This undoubtedly is why the record is sketchy and less than one would expect....") (Blackmun, J., concurring)

[15] *See also Thompson v. United States Dep't of Labor*, 885 F.2d 551, 555 (9th Cir. 1989) (quoting *Exxon*, 91 F.R.D. 26, 32 (N.D. Tex. 1981)); *Citizens for Envtl. Quality v. United States*, 731 F. Supp. 970, 982 (D. Colo. 1989) (finding that court may "supplement" record submitted by agency to reflect "whole record"); *Bar MK Ranches v Yeutter*, 994 F.2d 735, 739 (10th Cir. 1993) ("An agency may not unilaterally determine what constitutes the Administrative Record"); *National Wildlife Federation v. Burford*, 677 F.Supp. 1445, 1457 (D.Mont. 1985) ("An agency may not submit an administrative record

2.4 Extra-Record Technical Factors

It is inevitable that courts, called on to make judgments of reasonableness or of rationality, bring to the task myriad packets of information which could not possibly be reflected on the record. Assisting the courts in assembling such information, extra-record material is often required. In a number of cases, the federal courts have stated that a court, perplexed by the technical nature of an agency's decision, can develop extra-record evidence, but only as background to help it determine the adequacy of the original record. One clear example is *Arkla Exploration Co. v. Texas Oil & Gas Corporation*. In that case, information, not considered by the agency, was admitted to provide the court with a background on the issues:

> "The district court's admission of explanatory evidence served to help the court understand the complex nature of petroleum geology. It also served the related and equally important purpose of educating the court as to the kinds of scientific, technical, and economic data that are relevant to a legally correct [agency] determination." [16]

In *Portland Cement Ass'n*, 486 F.2d at 402, the court stated that "the necessity to review agency decisions, if it is to be more than a meaningless exercise, requires enough steeping in technical matters to determine whether the agency has exercised a reasoned discretion." Supplementation is proper in a case that "requires courts to delve into the scientific minutiae underlying agency rules to ascertain whether the agency considered all relevant factors and engaged in reasoned decision-making". *Nat'l Lime Ass'n v. EPA*, 627 F.2d 416, 453 (D.C. Cir. 1980).

There are other cases holding that courts may go beyond the record supplied by the agency to provide a court with background information due to the "highly technical nature of the subject matter," [17] and others which seem to endorse such a true exception in dicta.[18] In all of these

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to the court which contains only documents favoring the agency's decision and omits documents present in the agency's file which bear upon matters before the court")

[16] *Arkla Exploration Co. v. Texas Oil & Gas Corporation*, 734 F.2d 347, 357-60 (8th Cir. 1984) (also upholding district court's supplementation of record to explain record, among other reasons, to explain complex nature of petroleum geology, to educate court as to kinds of scientific, technical, and economic data which were relevant to decision, and ultimately to determine whether all relevant factors were considered, but not to substitute court's judgment on merits), cert. denied, 469 U.S. 1158 (1985);

[17] *Public Power Council v. Johnson*, 674 F.2d 791, 794 (9th Cir.1982); *American Canoe Assoc., Inc. v. EPA*, 46 F.Supp.2d 473, 477 (E.D.Va.1999) (acknowledging the need to supplement the record to explain or clarify technical terms or other difficult subject matter but requiring plaintiffs to (i) identify with

cases, supplementation was in order to provide technical background against which the rationality of the agency's decision can be assessed.

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particularity the nature of the extra-administrative record discovery needed and (ii) demonstrate a particularized need for the discovery sought, including a specification of the disputed material fact or facts to which the requested discovery pertains.); *Conservation Law Found. of New England v. Clark*, 590 F.Supp. 1467, 1474-75 & n. 5 (D.Mass.1984), aff'd sub nom. *Conservation Law Found. of New England v. Secretary of Interior*, 864 F.2d 954 (1st Cir.1989) (allowing augmentation to explain impact of environmental rules on Cape Cod seashore). *Love v. Thomas*, 858 F.2d 1347, 1356 (9th Cir. 1988) (specifically approving augmentation under technical background information exception), aff'g in part and rev'g in part on other grounds, 668 F. Supp. 1443, 1448-51 (D. Or. 1987) (allowing augmentation of record in order, among other reasons, to provide technical background on pesticides necessary to evaluate record); *Norwich Eaton Pharmaceuticals, Inc. v. Bowen*, 808 F.2d 486, 489 (6th Cir. 1987) (approving district court's consideration of evidence outside administrative record order to determine whether administrative record was adequate, citing need to assess consideration of relevant factors in highly technical case), cert. denied, 484 U.S. 816 (1987); *Association of Pac. Fisheries v. EPA*, 615 F.2d 794, 811-12 (9th Cir. 1980) (opinion by Anthony Kennedy, C.J.) (allowing direct court of appeals review of EPA decision, admitting into evidence studies done after agency decision as illuminating original decision); *Sierra Club v. U.S. Dep't of Transp.*, 695 F. Supp. 460, 463-64 (N.D. Cal. 1988) (considering plaintiff's declarations outside record for purposes of background information, but not on merits), rev'd on other grounds, 948 F.2d 568 (9th Cir. 1991); *MGPC, Inc. v. Duncan*, 581 F. Supp. 1047, 1059 (D. Wyo. 1984) (allowing introduction of plaintiff's affidavits and endorsing extra-record review for purposes of (1) aiding court in understanding issues, (2) giving court a background with which to better understand record, and (3) helping court to determine adequacy of record), rev'd on other grounds, 763 F.2d 422 (Temp. Emer. Ct. App.), cert. denied sub nom.; *MGPC, Inc. v. United States Dep't of Energy*, 474 U.S. 823 (1985); *Hiatt Grain & Feed, Inc. v. Bergland*, 446 F. Supp. 457, 467 (D. Kan. 1976), aff'd, 602 F.2d 929 (10th Cir. 1979), cert. denied, 449 U.S. 1073 (1980).

[18] *See Franklin Savings Ass'n v. Director, Office of Thrift Supervision*, 934 F.2d 1127, 1137-38 (10th Cir. 1991) (discussing exceptions to On the Record Rule, but limiting review to record which was adequate to allow effective review); *Environmental Defense Fund v. Costle*, 657 F.2d 275, 285-86 (D.C. Cir. 1981) (recognizing exception to exclusivity of administrative record where necessary to provide technical background necessary to understand agency's decision); *American Legion v. Derwinski*, 827 F. Supp. 805, 811-12 (D.D.C. 1993) (recognizing technical background exception but apparently admitting material only to explain what actually occurred in agency below), aff'd, 54 F.3d 789, (D.C. Cir. 1995), cert. denied, *American Legion v. Brown*, 116 S. Ct. 697 (1996); *Southern Utah Wilderness Alliance v. Thompson*, 811 F. Supp. 638, 642 n.4 (D. Utah 1993) (reviewing exceptions to On the Record Rule, to include material which explains "technical information in the record," but not allowing supplementation); *Abington Memorial Hosp. v. Heckler*, 576 F. Supp. 1081, 1087 n.3 (E.D. Pa. 1983) (acknowledging *Asarco* exceptions for background information or information bearing on consideration of relevant factors, but refusing to consider plaintiff's affidavit which goes to merits of agency's decision), aff'd, 750 F.2d 242 (3d Cir. 1984), cert. denied, 474 U.S. 863 (1985); *Saint James Hosp. v. Heckler*, 579 F. Supp. 757, 762 (N.D. Ill. 1984) (discussing plaintiff's arguments and applicable law which argues for admission of litigation affidavits to clarify original information before agency, but refusing to admit them because record was sufficient to decide case), aff'd, 760 F.2d 1460 (7th Cir.), cert. denied, 474 U.S. 902 (1985); *No Oilport! v. Carter*, 520 F. Supp. 334, 345-37 (W.D. Wash. 1981) (recognizing technical background information exception but actually justifying admission based on special nature of NEPA and on need for agency to explain its decision as required by Overton Park).

Finally, there is an important category of extra-record material that is not new factual material, but simply a recast of information from the agency's record. This may include further agency explanation of the materials it considered and how it used the materials to reason its result.[19] Similarly, challengers of agency rules are permitted to provide post-decisional explanatory material to characterize, process or analyze data in the record initially provided by the agency.[20] As analyzed above, this is completely consistent with *Overton Park* and does not involve an excursion beyond the record within the meaning of the Court's On the Record Rule. The language used by these courts, however, may often be cast as an approval of excursions beyond the record to develop factual material that supports or undercuts an agency's explanation of its decision:[21]

> "To a limited extent, therefore, the post-decision studies can be deemed a clarification or an explanation of the original information before the Agency, and for this purpose it is proper for us to consider them . . . . We do not think it is appropriate, however, for either party to use [such material] as a new rationalization for sustaining or attacking the agencies decision . . . it is inappropriate to rely on the specific conclusions of these studies to show that the [agency's action was] not the product of reasoned decision making"

2.5 Where post-decisional evidence shows whether agency action was correct or not

There are cases where evidence arising after the agency action shows whether the decision was correct or not. Courts have permitted supplementation not as hindsight means of second-guessing the agency but as corroboration of agencies' compliance (or lack thereof) with law. Notable cases are: *Association of Pac. Fisheries v. EPA*, 615 F.2d 794, 811-12 (9th Cir. 1980) ("If the post decisional studies showed that the Agency proceeded upon assumptions that were entirely fictional or utterly without scientific support, then post-decisional data might be utilized by the party challenging the regulation."); *Conservation Law Found. v. Clark*, 590 F. Supp. 1467, 1474-75 (D. Mass. 1984) (permitting both the agency and the plaintiffs to submit post-decisional supplemental evidence that subsequently becomes available when evidence either confirming or denying agency predictions made in the original decision. Also allowing supplementation of record to show factors agency should have considered, but did not).

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[19] *Arkla*, 734 F.2d 347 at 357-60.
[20] *See e.g.* MGPC, Inc. v. Duncan, 581 F. Supp. 1047, 1059 (D. Wyo. 1984)
[21] *Association of Pac. Fisheries v. EPA*, 615 F.2d 794, 811-12 (9th Cir. 1980).

Supplementation was also used to show that the agency was correct: *Amoco Oil v. EPA*, 501 F.2d 722, 731 (D.C. Cir. 1974) (noting that new data supplied by EPA helped court reach conclusion that EPA's original predictions had rational basis); *American Petroleum Inst. v. EPA*, 540 F.2d 1023, 1034 (10th Cir. 1976), cert. denied, 430 U.S. 922 (1977) ("In the instant case the record made before promulgation sustains the regulations. The new data is pertinent to show the validity of the EPA actions"). One might view these cases as not suggesting that post decisional studies could be admitted to undercut an agency's predictions, but rather as simply allowing a court to conclude that agency predictions were reasonable.

2.6 Judicial notice of facts outside the administrative record

There is a second way that relevant factor analysis might operate, wherein courts could go beyond the record in the standard way they can in on-the-record judicial proceedings: by means of judicial notice. There may be factors, not discussed in the record submitted to the court, whose relevance is so powerful and clear that a court may take judicial notice of them as factors not analyzed. For a court to take judicial notice of a fact, it must find that fact "not subject to reasonable dispute."[22] The "fact," in relevant factor analysis, would be of a second order, not the correctness of some proposition, but its nearly indisputable surface relevance--making it demand some sort of consideration from any rational decisionmaker. Publications or other known rules of the agency are a few examples of such facts.

[22] *Fed. R. Evid.* 201(b).

3 EXHIBIT 1 AND ITS APPENDICES ARE APPROPRIATELY BEFORE THE COURT TO ASSIST IN ITS JUSICIAL REVIEW

The Administrative Record as furnished by USPTO frustrates judicial review because it contains no explanatory material for its indigestible data. As shown in my Brief and further below, it is incomplete, as it does not contain all the information that the USPTO considered in making its decision. This is a deliberate or grossly negligent omission. For these reasons and others listed below, my Exhibits are directed at properly supplementing the record for judicial review.

3.1 Exhibit 1 and Appendices B and C are properly before the Court because they demonstrate that the USPTO considered evidence which it failed to include in the record.

Paragraphs 7-10 of my declaration in Exhibit 1 provide factual support to my assertions in Section 6 of my Brief that the USPTO new about certain workload reducing alternative proposals to its New Rules. They show the merits of Examination-On-Request system, which the USPTO had been aware of, and they show that the USPTO had actually considered such an alternative in some detail but failed to include it in the record. In its Regulatory Flexibility Act Study which it submitted to the record[23] ("RFA Study"), the USPTO admits that it considered such an alternative but it failed to include any evidence it relied on to reject such alternative: [24].

> "The USPTO .... notes that ***patent user groups*** have historically not favored increases in the deferral of examination. ***Therefore***, the final rule does not contain this alternative." (Emphasis added).

Appendix B constitutes factual support to Paragraphs 7-10 of Exhibit 1 and is therefore directed to the same subject matter and similarly admissible pursuant to the reasons stated in Section 2.3 above. Pages 20-22 of Appendix C as cited in my Brief, provide factual support and technical background tutorial on the proposed system of Examination-On-Request, explaining why the USPTO should have properly addressed it and is therefore admissible pursuant the reasons stated in Sections 2.2, 2.3 and 2.4. Appendix C contains tables and data made available by the USPTO during it Town-Hall meetings, which are part of the administrative record. It also contains data that was published by the USPTO in its reports, which cannot be "subject to reasonable dispute" and the court can take judicial notice of these facts. Furthermore, Appendix C in its entirety was provided to OMB during its consultation with the USPTO on the New Rules and, pursuant to Executive Order 12,866, was provided to the USPTO ***prior*** to the changes in the New Rules. It is therefore part of the ***full*** record and should have been provided by the USPTO. Further reasons for inclusion of these documents are described in Section 6 of my Brief.

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[23] USPTO, *Certification Analysis Under The Regulatory Flexibility Act*, by ICF International, (Produced by USPTO at A08270-A08306, published no earlier than August 28, 2007 at http://www.uspto.gov/web/offices/pac/dapp/opla/presentation/ccfrcertificationanalysis.pdf. .

[24] RFA Study, note 23, at 31.

3.2 Appendices A, D and E are properly before the court because they demonstrate that the USPTO failed to consider relevant factors and because they aid the Court in evaluating technical factors.

Appendix A provides a survey of search price quotes for an ESD in support of the study in Appendix E. The USPTO had a duty to assess these costs specifically in connection with its new ESD requirements and failed to do so because it did not submit its New Rules for public comment and because the estimates it produced in the RFA Study were based on examination support briefs with fewer than 5/25 claims. Thus, to the extent that Appendix A stands alone, it must be admitted pursuant the reasons stated in Sections 2.2 and 2.4. Appendix D is relied upon in Appendix E for the purposes of providing ESD cost estimates and the total national impact of such costs. As such it must also be admitted pursuant the reasons stated in Sections 2.2 and 2.4. Appendix E, similarly provides cost estimates of other portions of the New Rules not addressed by the USPTO. It provides sections demonstrating that the USPTO "entirely failed to consider relevant aspects of the problem" and therefore must similarly be admitted pursuant the reasons stated in Sections 2.2 and 2.4.

3.3 Appendices C and E are properly before the court as illustrating data already in the record provided by the USPTO

Much of the data provided by Appendices C and E is compiled from the administrative record and is thus admissible on this fact alone. It's utility is undisputed, as it provides single pictures that express what the USPTO provided in computer data dumps over hundreds of pages, which the Court cannot even begin to evaluate. These Appendices also contain data that was published by the USPTO in its reports, which cannot be "subject to reasonable dispute" and the court can take judicial notice of these facts. These Appendices serve in assisting the court in its determination of agency expertise and its relevance to the deference it seeks. Appendix E shows that no USPTO expertise in determining the economic or legal causes for the growth in claims and continuation should be presumed and that no deference to USPTO on such technical issues is warranted.

4 CONCLUSION

For the foregoing reasons, I, *amicus curiae* Ron D. Katznelson, oppose defendants' motion to strike my Exhibits and urge the Court to order their inclusion in its judicial review.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of February 2008, I sent for filing the foregoing with the Clerk of the Court, which upon entry will send electronic notification of such filing (NEF) to all counsel of record.

By: [signature]

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